**PATENT**
**Docket No.: 12013/48803**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| Inventor(s): | Richard S. KUSLEIKA | Group Art Unit: | 3763 |
| Appl'n No.: | 10/825,309 | Confirmation No.: | 7747 |
| Filing Date: | April 16, 2004 | Examiner: | Quynh-Nhu Hoang Vu |
| For: | CATHETER FOR TISSUE DILATATION AND DRUG DELIVERY | | |

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## AMENDED APPEAL BRIEF

S I R :

In response to the Notification of Non-Compliant Appeal Brief dated November 5, 2009, Appellant respectfully submits this Appeal Brief pursuant to 37 C.F.R. § 41.37.

The Commissioner is authorized to charge the fee of $540.00 under 37 C.F.R. § 41.20(b)(2) to Deposit Account No. 11-0600 and to charge that same account for any other applicable fee associated with this application.

## REAL PARTY IN INTEREST

The real party in interest is Boston Scientific Scimed, Inc., assignee of this application.

The inventor, Richard S. Kusleika, executed an assignment to Schneider (USA) Inc, which was recorded in the U.S. Patent & Trademark Office ("PTO") on October 10, 1996, at reel 8276, frame 0472. A document showing a change of corporate name from Schneider (USA) Inc to Boston Scientific Scimed, Inc. was recorded in the PTO on September 14, 2004, at reel 016430, frame 0343.

## RELATED APPEALS AND INTERFERENCES

There are no other prior or pending appeals, interferences or judicial proceedings known to Appellant, Appellant's legal representative, or the assignee that are related to, will directly affect, will be directly affected by, or will have a bearing on the Board's decision in the pending appeal.

## STATUS OF CLAIMS

The claims at issue on this appeal are claims 16-24, 38 and 39. The following chart lists the status of all claims:

| Claim | Status |
|---|---|
| 1-15 | Canceled |
| 16-24 | **Finally Rejected, at Issue on Appeal** |
| 25-37 | Canceled |
| 38-39 | **Finally Rejected, at Issue on Appeal** |

## STATUS OF AMENDMENTS

No amendments were filed after the final rejection of March 5, 2009, from which this appeal is taken. The pending claims that are the subject of this appeal are shown in the Claims Appendix to this brief.

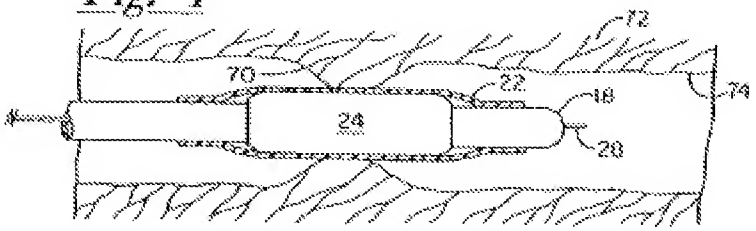
## SUMMARY OF CLAIMED SUBJECT MATTER

Claim 16 is the only independent claim at issue on this appeal. Claim 16 is directed to a process for treating tissue within a body lumen, such as, for example, a blood vessel. (Specification, para. [0038].)

The process can be described with reference to the example embodiment illustrated in FIGS. 1-7. With reference to those figures, the process comprises providing an elongate flexible catheter 18 having a flexible treatment sheath 22 mounted to a distal end region of the catheter 18 and a dilatation balloon 24 within the flexible treatment sheath 22. (Specification, paras. [0013], [0040].) The flexible treatment sheath 22 is formed of an elastic material, and the dilatation balloon 24 is formed of a substantially inelastic material. (Specification, paras. [0014], [0045], [0047].) These materials affect the way the flexible treatment sheath 22 and dilatation balloon 24 expand, as described below.

The process further comprises advancing the elongate flexible catheter 18 inside the body vessel until the flexible treatment sheath 22 is adjacent a predetermined treatment site 70. (Specification, para. [0051].) This is shown in FIG. 4, reproduced below:

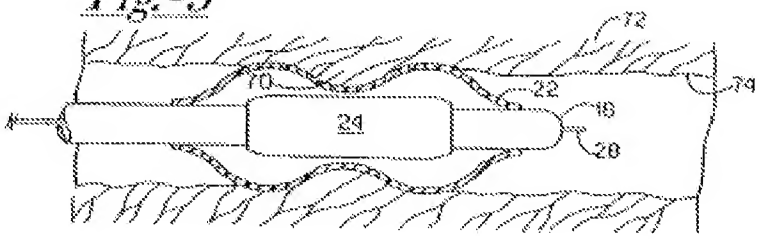
Fig. 4




The next step in the process is that, while maintaining the dilatation balloon 24 in an unexpanded condition, a treatment fluid is supplied under pressure to a compartment formed by the treatment sheath 22, to elastically expand the treatment sheath 22 into a substantially

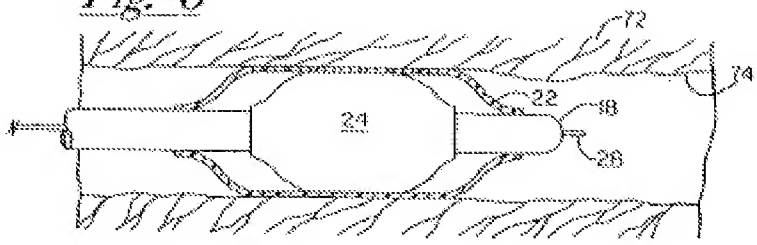
conforming contact with the surrounding tissue at the treatment site and cause the treatment fluid to pass through the treatment sheath 22 from the compartment to the surrounding tissue. (Specification, para. [0052].) The elasticity of the treatment sheath 22 enables the treatment sheath 22 to substantially conform to the tissue, as shown in FIG. 5, reproduced below:

Fig.-5

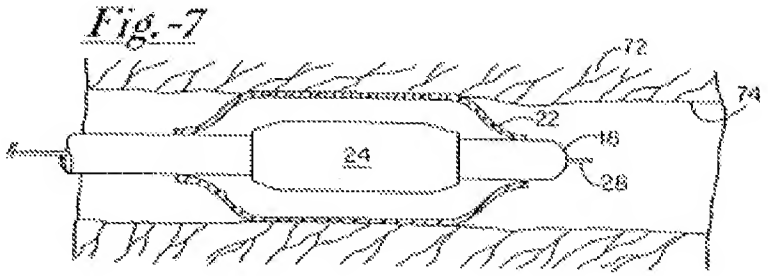



The next step in the process is that, while maintaining the treatment sheath 22 in substantially conforming contact with the surrounding tissue at the treatment site, the dilatation balloon 24 is expanded. The dilatation balloon 24 acts upon the surrounding tissue through the treatment sheath 22 to effect a dilatation or enlargement of the surrounding tissue. (Specification, para. [0053].) The inelasticity of the dilatation balloon 24 means that the dilatation balloon will maintain its generally cylindrical form and, with increased pressure, will press the occlusion to enlarge the body lumen. (Id.) This is shown in FIG. 6, reproduced below:

Fig.-6



Dependent claim 17 recites that, following the dilatation of the tissue, the dilatation balloon is radially contracted while the treatment sheath is maintained in contact with the tissue to administer the treatment fluid to the dilatated tissue. (Specification, para. [0054].) This is shown in FIG. 7, reproduced below:




Dependent claim 17 further recites that following the administering of the treatment fluid, the supply of the treatment fluid is discontinued to allow the treatment sheath to contract under a residual elastic force. (Specification, para. [0055].)

Dependent claim 38 recites that the treatment sheath is formed of a biocompatible elastomeric material consisting essentially of at least one of the following: latex, urethane, silicone, and a thermoplastic elastomer. (Specification, para. [0047].)

Dependent claim 39 recites that the biocompatible elastomeric material has a modulus of elasticity in the range of 2,000 to 80,000 psi and that the treatment sheath has a uniform thickness in the range of 0.5-5 mils, whereby the treatment sheath elastically expands into the substantially conforming contact. (Specification, para. [0047].)

## GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Are Claims 16-24, 38 and 39 rendered obvious under 35 U.S.C. § 103(a) by U.S. Patent No. 4,994,033 to Shockey et al. ("Shockey") in view of U.S. Patent No. 5,447,497 to Sogard et al. ("Sogard")?

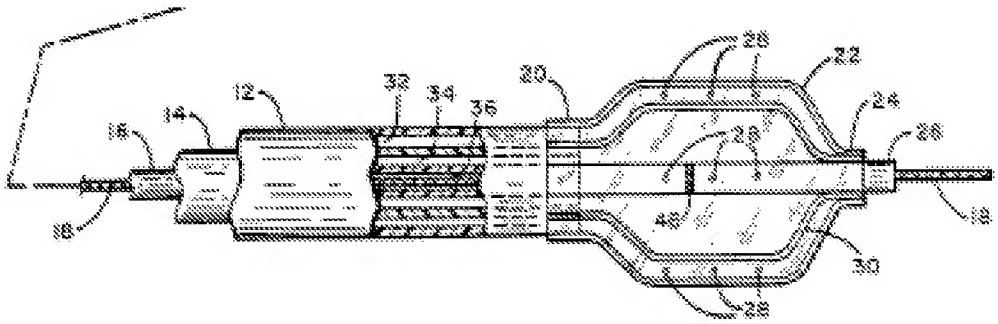
## ARGUMENT

**Group I (Claims 16, 19, 20, 21 and 24)**

Claim 16 stands rejected as allegedly being rendered obvious under 35 U.S.C. § 103(a) by U.S. Patent No. 4,994,033 to Shockey et al. ("Shockey") in view of U.S. Patent No. 5,447,497 to Sogard et al. ("Sogard").

The Shockey patent is commonly owned with the present application. The Appellant's specification specifically discusses the Shockey reference as background prior art. (Specification, para. [0004].)

Shockey discloses a catheter for drug delivery and tissue dilatation, as illustrated below:




The catheter has an inner expander member 30 and an outer expander member or sleeve 22. The outer expander member 22 of Shockey is substantially inelastic. In fact, the only materials that Shockey discloses for the outer expanded member 22 are polyethylene tetrathalate (PET) and polvinyl chloride (PVC). See Shockey, col. 3, lines 12-16 ("Where the expander member 22 comprises a biaxially oriented thermosetting plastic material such as polyethylene tetrathalate or polyvinyl chloride, the micropores 28 may be formed using a precision laser."). These same materials that Shockey discloses for its outer expander are among the inelastic

materials that the Appellant's specification discloses for the Appellant's inelastic inner balloon. (Specification, para. [0045] (disclosing PET and PVC for the inelastic balloon).)

The Shockey device is designed for, and used for, simultaneous delivery of a drug and dilatation of a vessel. This is in contrast to the Appellant's invention, in which the treatment sheath is first expanded into a substantially conforming contact with the tissue to deliver the treatment fluid, while maintaining the dilatation balloon in an unexpanded condition. In fact, Shockey specifically states that an object of Shockey's invention is to dilatate (expand) the vessel and deliver the drug at the same time. Shockey states:

> [An] object of the invention is to provide a dilatation catheter in which the stenotic lesion being treated can be spread and expanded at the same time that it is sprayed with a plaque reducing drug or a substance which forms a stent in situ.

(Shockey, col. 2, lines 3-7 (emphasis added).)

Shockey describes the use of its catheter as follows:

> Once the distal end of the catheter is appropriately positioned with the aid of a radiopaque marker band 46, the selected drug or other material is introduced through the proximal port 40 and through the lumen 32 and into the confines of the outer expander member 22. The injection of the drug will cause some enlargement of the outer expander member 22 but typically the pressure at which the drug material is injected is below the point where substantial amounts of the drug are ejected out through the micropores 28. To perform the simultaneous substance delivery and dilatation, an inflation fluid is next injected through the port 42 and thence through the lumen 34 into the interior of the expander sleeve 30. As the pressure is increased, typically approaching seven to ten atmospheres, the expander member inflates to its predetermined maximum diameter and, in doing so, forces the liquid substance through the ports 28 to effectively spray the lesion being treated with a particular drug or other material. The expansion of the inner sleeve 30 also results in pressure being exerted against the lesion, forcing it against the vessel wall as the drug or other substance is delivered. The combination of the dilatation pressure and the drug substance release will been [*sic* be] found to be

> effective in providing long-term patency to the treated blood vessel.

(Shockey, col. 3, line 67-col. 4, line 24 (emphasis added).)

Shockey also states:

> [A]s the pressure is increased within the innermost sleeve causing it to "balloon" out, the drug is simultaneously forced through the micro-apertures to spray and bathe the lesion being treated with the medicament or substance.

(Shockey, col. 2, lines 39-44 (emphasis added).)

Shockey differs from the invention of Appellant's claim 16 for at least two important reasons. First, Shockey does not disclose a flexible treatment sheath "formed of an elastic material." Second, Shockey does not disclose the step of "while maintaining the dilatation balloon in an unexpanded condition, supplying a treatment fluid under pressure to a compartment formed by the treatment sheath, to elastically expand the treatment sheath radially into a substantially conforming contact with the surrounding tissue at the treatment site [and] cause the treatment fluid to pass through the treatment sheath from the compartment to the surrounding tissue."

In Shockey, as described above, the outer expander member 22 is formed of an inelastic material. In addition, the outer treatment sheath 22 of Shockey is not expanded into substantially conforming contact with the surrounding tissue while maintaining the dilatation balloon in an unexpanded condition. In Shockey, the outer expander member 22 is not expanded into contact with the surrounding tissue until Shockey's inner sleeve 30 is expanded.

The Appellant's specification explains the advantages of Appellant's invention over a device and method such as disclosed by Shockey. Appellant's specification states:

> [T]he growing interest in gene therapy for treating cardiovascular diseases including restenosis, and the nature of coronary arteries, raise challenges not yet adequately addressed.
>
> More particularly, gene therapy involves large, complex molecules that tend to rapidly combine with proteins in the bloodstream to lose their efficacy. This raises a need to protect gene therapy agents from contact with the blood as they are maintained in contact with a vessel wall under treatment. Similarly, a freshly cracked lesion can be more effectively medicated if it is protected from contact with blood during treatment.
>
> * * *
>
> Several performance advantages arise from the greater elasticity [of the outer treatment sheath] and resulting conformity to the tissue. First, wall segment 86 and the arterial tissues are contiguous over a much greater surface area. As a result a fluid tight seal is formed over the sheath/tissue interface, preventing blood from contacting tissue that is contiguous with the sheath. The prevention of contact with blood, particularly as to freshly cracked lesions, may considerably reduce the probability of restenosis.
>
> Second, the seal enhances concentration of the therapeutic agent along the interface, more specifically that portion of the sheath/tissue interface where pores 56 are formed through the sheath. Improved concentration reduces the amount of the agent needed for effective treatment, and reduces potential toxicity concerns.
>
> Third, the fluid tight seal effectively isolates the therapeutic agent and blood from one another, preventing the loss of efficacy in certain agents caused by contact with blood.

(Specification, paras. [0006]-[0007], [0059]-[0061].)

In the Shockey method, the outer expander member is not in conforming contact with the surrounding tissue when the inner expander 30 is expanded. As a result, as Shockey itself describes, when the inner expander 30 is expanded, it "forces the liquid substance through the ports 28 to effectively spray the lesion being treated with a particular drug or other material." (Shockey, col. 4, lines 12-17 (emphasis added).)

The Appellant's invention avoids Shockey's "spraying" or "jetting" effect. It also allows a more uniform pressure of the therapeutic agent. Appellant's specification states:

> The administration of the therapeutic agent while dilatation balloon 24 is evacuated … improves the therapy in several respects, as compared to prior arrangements in which the dilatation balloon must be inflated to force the therapeutic agent radially outward through a perforated delivery balloon. First, the flow rate of therapeutic agent through the sheath is more effectively controlled by direct control of the fluid pressure of the therapeutic agent, rather than indirect control through expansion of the dilatation balloon. The much lower pressures at which the agent is administered improve control and avoid arterial wall damage from "jetting". Secondly, the evacuated dilatation balloon occupies less space within compartment 52, leaving a larger proportion of the compartment volume occupied by the therapeutic agent. This results in more uniform fluid pressure (of the agent) throughout compartment 52, and avoids unwanted localized contact of the dilatation balloon with radially inward portions of the sheath. This leads to a more uniform flow of the agent through the sheath into tissue.

(Specification, para. [0063] (emphasis added).)

The Sogard reference does not make up for the deficiencies of Shockey. The Sogard reference does not provide any suggestion or reason for modifying the Shockey procedure such that Shockey's outer sleeve 22 is expanded "into a substantially conforming contact with the surrounding tissue at the treatment site" prior to expansion of the inner sleeve 30. In fact, Sogard is relied upon in the Final Office Action solely for making the inner sleeve of Shockey of an inelastic material. The Final Office Action states, "It would have been obvious … to modify the device of Shockey with a dilatation balloon made of an inelastic material, as taught by Sogard." (Final Office Action, March 5, 2009, p. 3.) The Final Office Action does not say why a person of ordinary skill in the art would choose an "elastic" material for the outer sleeve of Shockey.

More importantly, the Final Office Action does not even address modifying the Shockey procedure such that Shockey's outer sleeve 22 is expanded "into a substantially conforming

contact with the surrounding tissue at the treatment site" prior to expansion of the inner sleeve 30. Such a modification would be contrary to the Shockey disclosure, which explicitly states that its drug delivery from the outer sleeve and vessel dilatation from the inner sleeve should be "simultaneous" and "at the same time." (Shockey, col. 2, lines 5 & 41; col. 4, lines 8-9.) Because Shockey's "simultaneous" process cannot be modified to Appellant's claimed two-step process without destroying the explicit teachings of Shockey, and because such a modification is nowhere suggested by the prior art, the rejection of claim 16 should be reversed.

In addition, in Appellant's invention, the outer treatment sheath is "elastic" and the balloon is "substantially inelastic" for the purpose of enabling the two-step process whereby the outer treatment sheath is initially expanded "into a substantially conforming contact with the surrounding tissue at the treatment site" for drug delivery and the balloon is later separately expanded "to effect a dilatation of the surrounding tissue." Shockey, which neither discloses nor even hints at Appellant's two-step process, also does not disclose using different materials for the inner and outer members, much less different materials as claimed in Appellant's claims. Shockey does not state, suggest or even hint at making the expander member 22 and the inner sleeve 30 of different materials, much less making the expander member 22 and the inner sleeve 30 of different materials such that the expander member can be fairly characterized as "elastic" in comparison to a substantially inelastic inner sleeve.

Thus, for the foregoing reasons, the rejection of claim 16, and all claims depending therefrom, should be reversed.

**Group II (Claims 17, 18, 22 and 23)**

Dependent claim 17 recites that, following the dilatation of the tissue, the dilatation balloon is contracted while the treatment sheath is maintained in contact with the tissue to

administer the treatment fluid to the tissue. Nothing in Shockey or Sogard suggests maintaining Shockey's outer expander in contact with tissue and delivering treatment fluid after the inner member is contracted. In fact, as stated above, since Shockey explicitly states that its drug delivery and tissue dilatation are "simultaneous" and "at the same time," it would be contrary to the Shockey reference for drug delivery to occur after contraction of the inner dilatation member.

Thus, for the foregoing reasons, the rejection of claim 17 and all claims depending therefrom should be reversed.

**Group III (Claims 38 and 39)**

Dependent claim 38 recites that the treatment sheath is formed of a biocompatible elastomeric material consisting essentially of at least one of the following: latex, urethane, silicone, and a thermoplastic elastomer. As stated above, the only materials that Shockey discloses for its outer expander member 22 are the inelastic materials polyethylene tetrathalate (PET) and polvinyl chloride (PVC). (Shockey, col. 3, lines 12-16.) The Final Office Action points to column 3, lines 12-16, of Shockey for the rejection of claim 38. (Final Office Action, March 5, 2009, p. 4.) However, this passage in Shockey discloses only inelastic PET and PVC, not an elastic latex, urethane, silicone, or thermoplastic elastomer as recited in claim 38. The cited passage does not support the rejection. Thus, for the foregoing reasons, the rejection of claim 38, and claim 39, which depends from claim 38, should be reversed.

## CONCLUSION

For the foregoing reasons, the Appellant respectfully requests favorable consideration of this appeal by the Board and reversal of the final rejection of claims 16-24, 38 and 39.

The Office is hereby authorized to charge any additional fees under 37 C.F.R. §1.16 or §1.17 or credit any overpayment to Deposit Account No. 11-0600.

Respectfully submitted,

Date: December 2, 2009

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## CLAIMS APPENDIX

The claims read as follows:

1.-15. (Canceled)

16. (Previously Presented) A process for treating tissue at a treatment site within a body lumen, comprising:

providing an elongate flexible catheter having a flexible treatment sheath mounted to a distal end region of the catheter and a dilatation balloon within the flexible treatment sheath, wherein the flexible treatment sheath is formed of an elastic material and the dilatation balloon is formed of a substantially inelastic material;

intraluminally advancing the elongate flexible catheter until the flexible treatment sheath is adjacent a predetermined treatment site;

while maintaining the dilatation balloon in an unexpanded condition, supplying a treatment fluid under pressure to a compartment formed by the treatment sheath, to elastically expand the treatment sheath radially into a substantially conforming contact with the surrounding tissue at the treatment site, cause the treatment fluid to pass through the treatment sheath from the compartment to the surrounding tissue, and maintain the treatment sheath expanded into said contact; and

while maintaining the treatment sheath in said substantially conforming contact with the surrounding tissue at the treatment site, radially expanding the dilatation balloon within the compartment, whereby the dilatation balloon acts radially upon the surrounding tissue through the treatment sheath to effect a dilatation of the surrounding tissue.

17. (Previously Presented) The process of claim 16 further comprising:

following said dilatation, radially contracting the dilatation balloon while maintaining the treatment sheath in said contact to administer the treatment fluid to the dilatated tissue; and

following said administering of the treatment fluid, discontinuing the supplying of the treatment fluid to allow the treatment sheath to radially contract under a residual elastic force.

18. (Previously Presented) The process of claim 17 further comprising:

after allowing the treatment sheath to radially contract, proximally withdrawing the catheter from the body lumen.

19. (Original) The process of claim 16 wherein:

said advancing of the catheter includes intraluminally positioning a guidewire with a distal end thereof outside of the body, inserting the proximal end of the guidewire within the distal end of a guidewire lumen running through the catheter, and advancing the catheter distally relative to the guidewire.

20. (Previously Presented) The process of claim 16 wherein:

said supplying of the treatment fluid comprises providing the treatment fluid to the compartment via treatment fluid supply lumen of the catheter at a predetermined treatment fluid pressure.

21. (Previously Presented) The process of claim 20 wherein:

said supplying of the treatment fluid comprises causing the treatment fluid to perfuse through multiple pores in said treatment sheath.

22. (Previously Presented) The process of claim 17 wherein:

said dilatation balloon radially enlargeable by supplying a dilatation fluid to a dilatation chamber formed by the balloon and the catheter, and wherein said contraction of the dilatation balloon comprises withdrawing the dilatation fluid from the dilatation chamber to substantially evacuate the dilatation balloon.

23. (Previously Presented) The process of claim 17 wherein:

said allowing the treatment sheath to radially contract comprises withdrawing the treatment fluid from the compartment.

24. (Previously Presented) The process of claim 16 further comprising:

while maintaining the treatment sheath in said substantially conforming contact, allowing a flow of body fluids through the catheter past the treatment site.

25.-37. (Canceled)

38. (Previously Presented) The process of claim 16, wherein said treatment sheath is formed of a biocompatible elastomeric material consisting essentially of at least one of the following: latex, urethane, silicone, and a thermoplastic elastomer.

39. (Previously Presented) The process of claim 38, wherein the biocompatible elastomeric material has a modulus of elasticity in the range of 2,000 to 80,000 psi, said sheath has a uniform thickness in the range of 0.5-5 mils, whereby the treatment sheath elastically expands into said substantially conforming contact.

## EVIDENCE APPENDIX

Other than the specification, drawings, claims, and the references relied upon by the Examiner, there is no other evidence being relied upon by the Appellant in this appeal.

## RELATED PROCEEDINGS APPENDIX

[NONE]